

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in December 2014.

## Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

### ANADA Number: 200-575

Trade Name: Carprofen Chewable Tablets  
Pioneer: Rimadyl®  
Ingredients: Carprofen  
Sponsor: Putney, Inc.  
Approval Date: December 17, 2014  
Status: Rx  
Route: Oral  
Species: Dogs  
Drug Form: Scored chewable tablet  
Concentration: 25 mg, 75 mg, and 100 mg tablets  
Indications: For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

## Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

### NADA Number: 141-034

Trade Name: Gainpro®  
Ingredients: Bambermycins  
Sponsor: Huvepharma AD  
Approval Date: December 11, 2014

This supplement provides for establishment of a Type C free-choice loose mineral without selenium for increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers).

### NADA Number: 141-232

Trade Name: Simplicef®  
Ingredients: Cefpodoxime proxetil  
Sponsor: Zoetis Inc.  
Approval Date: December 16, 2014

This supplement provides for the addition of a flavored, chewable tablet.

### NADA Number: 141-276

Trade Name: Zilmax® plus Rumensin® plus Tylan®  
Ingredients: Zilpaterol hydrochloride 4.8%, monensin, USP; and tylosin phosphate  
Sponsor: Intervet, Inc.  
Approval Date: December 15, 2014

This supplement provides for: 1) component feeding of 60 mg zilpaterol hydrochloride/head/day in combination with feed containing monensin and tylosin phosphate for increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle fed in confinement for slaughter during the last 20 to 40 days on feed, and 2) adding the following

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statement to the labeling for the use of zilpaterol hydrochloride in complete feed when fed in combination with monensin and tylosin phosphate: "CAUTION: Not to be fed to cattle in excess of 90 mg/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed."

### NADA Number: 141-068

Trade Name: Baytril® 100 Injectable Solution  
Ingredients: Enrofloxacin  
Sponsor: Bayer HealthCare LLC  
Approval Date: December 23, 2014

This supplement provides for 1) the control of *colibacillosis* in groups or pens of weaned pigs where *colibacillosis* associated with *Escherichia coli* has been diagnosed, and 2) for intramuscular injection in swine.

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## Sponsor Change

### (A)NADA Numbers: 139-236, 140-866, 140-994, 200-055, 200-332

Previous: Lloyd, Inc.  
New Sponsor: Akorn Animal Health, Inc.  
Drug Labeler Code: 053599

### (A)NADA Numbers: 141-431, 200-266, 200-432

Previous: Bioniche Animal Health USA, Inc.  
New Sponsor: Vetoquinol USA, Inc.  
Drug Labeler Code: 017030

### (A)NADA Numbers: 065-252

Previous: Veterinary Service, Inc.  
New Sponsor: Huvepharma AD  
Drug Labeler Code: 016592

### (A)NADA Numbers: 141-272

Previous: Elanco Animal Health, Inc., A Division of Eli Lilly & Co.  
New Sponsor: Nexcyon Pharmaceuticals, Inc.  
Drug Labeler Code: 050929

### (A)NADA Numbers: 200-026, 200-154, 200-295, 200-314, 200-354, 200-356, 200-357, 200-358, 200-359, 065-480, 138-934, 138-935, 138-938, 138-939, 140-680, 140-681, 141-137

Previous: Pennfield Oil Co.  
New Sponsor: Pharmgate LLC  
Drug Labeler Code: 069254

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## Patent Additions

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The following corrections or additions to the list were completed in December 2014.

### **NADA Number: 141-339**

Patent number: 8,905,913

Expiration Date: July 28, 2030

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## **Withdrawal of Approval**

### **ANADA Number: 200-305**

Sponsor: Vetoquinol N.-A., Inc.

Trade Name: Oxytetracycline Hydrochloride Soluble Powder

Ingredients: Oxytetracycline hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 520.1660d*

*79 FR 74021*